

- 1 of 2 -

ID - For Official Use Only

VIII. Type of Regulated Waste Activity (Mark 'X' in the appropriate boxes. Refer to Instructions)

A. Hazardous Waste Activity

1. Generator (See Instructions)
- ☐ a. Greater than 1000kg/mo (2,200 lbs.)
- ☒ b. 100 to 1000 kg/mo (220-2,200 lbs.)
- ☐ c. Less than 100 kg/mo (220 lbs.)
2. Transporter (Indicate Mode in boxes 1-5 below)
- ☐ a. For own waste only
- ☐ b. For commercial purposes
- Mode of Transportation
- ☐ 1. Air
- ☒ 2. Rail
- ☐ 3. Highway
- ☐ 4. Water
- ☐ 5. Other - specify _____
- ☐ 3. Treater, Storer, Disposer (at installation) Note: A permit is required for this activity, see instructions.
4. Hazardous Waste Fuel
- ☐ a. Generator Marketing to Burner
- ☐ b. Other Marketers
- ☐ c. Boiler and/or Industrial Furnace
- ☐ 1. Smelter Deferral
- ☐ 2. Small Quantity Exemption
- Indicate Type of Combustion Device(s)
- ☐ 1. Utility Boiler
- ☐ 2. Industrial Boiler
- ☐ 3. Industrial Furnace
- ☐ 5. Underground Injection Control

B. Used Oil Recycling Activities

1. Used Oil Recycling Marketer
- ☐ a. Marketer Directs Shipment of Used Oil to Off-Specification Burner
- ☐ b. Marketer Who First Claims the Used Oil Meets the Specifications
2. Used Oil Burner - Indicate Type(s) of Combustion Device
- ☐ a. Utility Boiler
- ☐ b. Industrial Boiler
- ☐ c. Industrial Furnace
3. Used Oil Transporter - Indicate Type(s) of Combustion Device(s)
- ☐ a. Transporter
- ☐ b. Transfer Facility
4. Used Oil Processor/Re-refiner - Indicate Type(s) of Activity(ies)
- ☐ a. Process
- ☐ b. Re-refine

IX. Description of Regulated Wastes (Use additional sheets if necessary)

A. Characteristics of Nonlisted Hazardous Wastes. (Mark 'X' in the boxes corresponding to the characteristics of nonlisted hazardous wastes your installation handles; See 40 CFR Parts 261.20 - 261.24)

1. Ignitable (D001) ☒
2. Corrosive (D002) ☐
3. Reactive (D003) ☐
4. Toxicity Characteristic (List specific EPA hazardous waste number(s) for the Toxicity characteristic contaminant(s))
- ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

B. Listed Hazardous Wastes. (See 40 CFR 261.31 - 33; See instructions if you need to list more than 12 waste codes.)

1	2	3	4	5	6
F005					
7	8	9	10	11	12

C. Other Wastes. (State or other wastes requiring a handler to have an I.D. number; See instructions.)

1	2	3	4	5	6

X. Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Signature

Blud Webb

Name and Official Title (Type or print)

Purchasing Agent

Date Signed

5/4/98

XI. Comments

CFN: Organon Teknika Corp BAH/MS 5/8/98 /lll

Note: Mail completed form to the appropriate EPA Regional or State Office. (See Section III of the booklet for addresses.)



For Official Use Only

$$\frac{C}{C}$$

Date Received
(yr. mo. day)

C
F

PAD174204792	T/A	C
		1

T/A	C
1	1

O	R	G	A	N	O	N	T	E	K	N	I	K	A	C	O	R	P	O	R	A	T	I	O	N
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

$$\frac{C}{3}$$

1	2	3	0	W	I	L	S	O	N	D	R	I	V	E
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

C

City or Town									
U	E	S	T		C	H	E	S	T

State	
P	A

ZIP Code

1	9	3	8	0
---	---	---	---	---

$$\frac{C}{5}$$

S	A	M	E
---	---	---	---

C

[illegible]

State

ZIP Code
$$\frac{C}{2}$$

C	H	I	L	D	E	R	S		D	A	N		M	G	R		Q	A	2	1	5	4	3	1	8	6	0	8
---	---	---	---	---	---	---	---	--	---	---	---	--	---	---	---	--	---	---	---	---	---	---	---	---	---	---	---	---

<u>C</u>
R

A	K	Z	O
---	---	---	---

H

☒ 1a. Generator ☒ 1b. Less than 1,000 kg/mo.

☐ 2. Transporter

☐ 3. Treater/Storer/Disposer

☐ 4. Underground Injection

☐ 5. Market or Burn Hazardous Waste Fuel

029 Chester

(enter 'X' and mark appropriate boxes below)

☐ a. Generator Marketing to Burner

☐ b. Other Marketer

☐ c. Burner

☐ a. Generator Marketing to Burner

☐ b. Other Marketer

☐ c. Burner

☐ 7. Specification Used Oil Fuel Marketer (or On site Burner)
Who First Claims the Oil Meets the Specification

☐ C. Industrial Furnace☐ A. Air ☐ B. Rail ☐ C. Highway ☐ D. Water ☐ E. Other (specify) _____

Mark 'X' in the appropriate box to indicate whether this is your installation's first notification of hazardous waste activity or a subsequent notification. If this is not your first notification, enter your installation's EPA ID Number in the space provided below.

☒ A. First Notification ☐ B. Subsequent Notification (*complete item C*)

C. Installation's EPA ID Number

ID — For Official Use Only															
C														T/A	C
W															1

X. Description of Hazardous Wastes (continued from front)

A. Hazardous Wastes from Nonspecific Sources. Enter the four-digit number from 40 CFR Part 261.31 for each listed hazardous waste from nonspecific sources your installation handles. Use additional sheets if necessary.

1	2	3	4	5	6
7	8	9	10	11	12

B. Hazardous Wastes from Specific Sources. Enter the four-digit number from 40 CFR Part 261.32 for each listed hazardous waste from specific sources your installation handles. Use additional sheets if necessary.

13	14	15	16	17	18
19	20	21	22	23	24
25	26	27	28	29	30

C. Commercial Chemical Product Hazardous Wastes. Enter the four-digit number from 40 CFR Part 261.33 for each chemical substance your installation handles which may be a hazardous waste. Use additional sheets if necessary.

31 P 0 5 8	32 P 1 0 5	33 P 1 0 6	34 P 1 1 5	35 U 0 0 2	36 U 0 0 3
37 U 0 0 7	38 U 0 4 4	39 U 2 4 6	40 U 1 1 6	41 U 1 5 4	42 U 1 5 5
43 U 2 4 7	44 U 1 5 4	45 U 1 8 8	46 U 2 1 3	47 U 2 3 6	48

D. Listed Infectious Wastes. Enter the four-digit number from 40 CFR Part 261.34 for each hazardous waste from hospitals, veterinary hospitals, or medical and research laboratories your installation handles. Use additional sheets if necessary.

49	50	51	52	53	54

E. Characteristics of Nonlisted Hazardous Wastes. Mark 'X' in the boxes corresponding to the characteristics of nonlisted hazardous wastes your installation handles. (See 40 CFR Parts 261.21 — 261.24)

☒ 1. Ignitable
(D001)

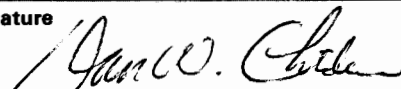
☒ 2. Corrosive
(D002)

☒ 3. Reactive
(D003)

☒ 4. Toxic
(D000)

XI. Certification

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

Signature 	Name and Official Title (type or print) Dan W. Childers, Manager QA	Date Signed 1/24/89
--	--	------------------------



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF LAND RECYCLING AND WASTE MANAGEMENT

Inspection Date 4-8-01
Time Start _____
Time Finish _____

HAZARDOUS WASTE INSPECTION REPORT

☐ GENERATOR☒ S Q GENERATOR

Temp ID PADEP0011243

Company name Synthes Development Center S.H.D. Number PADEP0011243Site Address 1230 Wilson Drive West Chester, PACounty Chester Municipality West Chester Zip 19380Name of Inspector Andrew SinclairName & Title of Responsible Official Mr. Bryan Lee, E.H.S.Person Interviewed SEA Telephone () _____

Mailing Address (if different from above) _____

Amount of Hazardous Waste Generated per Month: just beginning Pounds notified 2200 - 2300 Kgs lbs/mo

1. Site Characterization:

STORAGE: ☒ Container ☐ Tanks ☐ Containment Bldg. ☐ Drip Pad Other _____PBR: ☐ Neutralization/WWTP ☐ Reclaim Other _____GENERATOR TREATMENT ☐ Containers ☐ Tanks ☐ Containment Bldg. ☐ Drip Pad2. Universal Waste: ☐ Large Quantity Handler ☐ Small Quantity Handler

Universal Waste Types _____

3. Hazardous Waste Transporters:

Transporter Name Ties License Number PAAH 0680Transporter Name Eldredge, Inc License Number _____

Transporter Name _____ License Number _____

4. Types of hazardous waste generated and destination facility (location & type).

Waste Code	Waste Description	Destination Facility
<u>F003, F005, D001</u>	<u>Wet Flamm Liquid</u>	<u>Tecris LLC</u>
	<u>(acetone, methanol)</u>	<u>El Dorado, AR</u>
		<u>AR0069748192</u>
<u>D002, D001</u>	<u>Wet Flamm Lq</u>	<u>"</u>
	<u>(ethanol, phosphoric acid)</u>	
<u>D002</u>	<u>Wet Corrosive Liquid</u>	<u>"</u>
	<u>(hydrochloric acid)</u>	

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF LAND RECYCLING AND WASTE MANAGEMENT

HAZARDOUS WASTE INSPECTION REPORT GENERATORS -- SMALL QUANTITY GENERATORS

Site Name Synthes Development Co. ID Number PAD174204792 Date 4-8-04

1 - No Violation Observed 2 - Not Applicable 3 - Not Determined 4 - Non Compliance

STATUS

1	2	3	4	REQUIREMENT	PA CIT. 25 PA Code	FED. CIT. 40 CFR	LINE NO.
<input checked="" type="checkbox"/>				Hazardous waste determination performed on all waste streams	262a.10	262.11	H001
<input checked="" type="checkbox"/>				Identification Number	262a.10	262.12	H002
<input checked="" type="checkbox"/>				Authorized transporters only	262a.10	262.12(c)	H003
<input checked="" type="checkbox"/>				Subsequent notification requirements met	262a.12(b)		H004
<input checked="" type="checkbox"/>				Proper manifest used	262a.10	262.21	H005
<input checked="" type="checkbox"/>				Manifests filled out correctly and completely	262a.20		H006
<input checked="" type="checkbox"/>				Manifests signed and routed properly	262a.23(a)	262.23	H007
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			Generator waste accumulated on site for 90 days or less	262a.10	262.34(a)	H008
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			SQG waste accumulated on site for 180 days max unless 200 mile distance rule applies - 270 days	262a.10	262.34(e)(f)	H009
<input checked="" type="checkbox"/>				SQG waste accumulated on-site never exceeds 6000 kg	262a.10	262.34(e)(f)	H010
<input checked="" type="checkbox"/>				Satellite accumulation requirements complied with	262a.10	262.34(c)	H011
<input checked="" type="checkbox"/>				Personnel training program per 265.16 complied with	262a.10	262.34(a)(4) 262.34(d)	H012
<input checked="" type="checkbox"/>				Manifest exception and biennial reports retained for 3 years	262a.10	262.40(a)(b)	H013
<input checked="" type="checkbox"/>				Specified records retained for three years	262a.10	262.40(c)	H014
	<input checked="" type="checkbox"/>			Biennial reports submitted to the Department (LQG only)	262a.41	262.41	H015
<input checked="" type="checkbox"/>				Exception reporting procedures followed	262a.42	262.42	H016
<input checked="" type="checkbox"/>				Spill reporting procedures followed	262a.10	262.34(d)	H017
<input checked="" type="checkbox"/>				PPC plan developed and implemented	262a.10	262.34(a)	H018
	<input checked="" type="checkbox"/>			Special requirements followed for international shipments	262a.10	262.50 262.60	H019
	<input checked="" type="checkbox"/>			Source reduction strategy prepared and available (LQG only)	262a.100		H020
<input checked="" type="checkbox"/>				Excluded waste complies with exclusionary requirements	261a.4	261.4	H021

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF LAND RECYCLING AND WASTE MANAGEMENT

HAZARDOUS WASTE INSPECTION REPORT GENERATORS -- SMALL QUANTITY GENERATORS FACILITY SPECIFICS

Site Name Synthes Development Center ID Number PAD174204772 Date 4-8-04

1 - No Violation Observed 2 - Not Applicable 3 - Not Determined 4 - Non Compliance

STATUS

1	2	3	4	REQUIREMENT	PA CIT. 25 PA Code	FED CIT. 40 CFR	LINE NO.
				CONTAINERS (Subchapter I)			
X				Containers managed in compliance with 40 CFR Part 265 Subpart I and 25 PA Code Chapter 265a Subchapter I	262a.10	262.34	H025
X				Containers of hazardous waste in good condition	265a.1	265.171	H026
X				Containers and stored waste compatible	265a.1	265.172	H027
X				Containers kept closed except during addition or removal of wastes	265a.1	265.173(a)	H028
X				Containers managed to prevent leaks	265a.1	265.173(b)	H029
X				Container configuration and spacing insures safe management and access for inspection purposes and emergency equipment	265a.173		H030
		X		Container storage areas inspected at least weekly	265a.1	265.174	H031
X				Special requirements for ignitable or reactive and incompatible waste complied with	265a.1	265.176-177	H032
		X		Proper containment and collection systems in place	265a.179		H033
X				Air emission standards complied with (AA, BB, CC)	265a.1	265.178	H034
X				Containers clearly marked with accumulation date and visible for inspection	262a.10	262.34(a)(2)	H035
X				Containers labeled "Hazardous Waste"	262a.10	262.34(a)(3)	H036
X				Containers labeled accurately identify contents	SWMA 6018.403(b) (2)		H037

** no haz waste containers stored on site during inspection except one container storing a broken Hg thermometer.*

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF LAND RECYCLING AND WASTE MANAGEMENT

INSPECTION REPORT COMMENTS

Date of inspection 04 - 08 - 2004 Identification Number PAD174204792 / Temp# PADEP0011243
Company/Facility/Site Name Synthes Development Center

On April 8, 2004, I (Andrew Sinclair) conducted a routine small quantity generator of hazardous waste inspection of Synthes Development Center located at 1230 Wilson Dr. West Chester, PA 19380 in West Goshen Township. Mr. Bryan Lee was present during the inspection. Organon Teknika Corp had once operated at this address as indicated in the EPA database as a SQG of hazardous waste. The Synthes facility, a bio-technical company, has resided here for just over a year. Production has generally occurred only during the past two months. The facility manufactures bone cement. Mr. Lee had just recently notified the EPA that the facility was a SQG on February 25, 2004 as indicated on a copy of the form.

Hazardous wastes generated on-site include an alcohol solvent from the QC lab and an ethanol/phosphoric acid mixture. The hazardous waste hydrochloric acid disposed is expected only to be a one-time occurrence. The hazardous wastes are collected within labeled five-gallon close-top poly pails. When full, these containers are stored within a flammable locker in the hazardous materials room. The room is designed as its containment with the floor and wall-floor joints sealed. However the exit to the outside is not properly sealed. Mr. Lee had recently used a sealed berm for the interior door as a test and was satisfied. A similar sealed berm will be used for the doorway to the exterior of the building so as to comply with *PA Code 265a.179*. One pail of hazardous waste mercury from a broken thermometer was observed. The facility should ensure compliance with the hazardous waste satellite accumulation regulations. The labs were observed from the window. To enter the labs, one would need to don appropriate protective clothing (mask, glasses, cap, and gown).

Hazardous waste had recently been transported off-site on April 6, 2004 totaling 1120 pounds, however, this weight or volume is not expected to continue on a monthly basis. As a result of many tests during the initial production processes, these wastes were generated.

Weekly inspections of the hazardous waste storage area have not yet begun so as to comply with *40 CFR 265.174*. As a note, hazardous waste generated had recently begun. Mr. Lee intends to use the same format as used in the other Synthes facility in East Goshen.

Employee training for the site is equivalent to the employee training at the East Goshen Synthes site and meets the SQG standards.

The PPC plan was reviewed. The responsibilities of the emergency response coordinator are included. Emergency phone numbers for the Department (484-250-5900), the NRC, and PEMA are not included. These numbers should be incorporated.

Sharps from the labs, product development and quality check labs, are managed as infectious waste and manifested as pathological waste so as to ensure incineration. The sharps are placed in rigid plastic containers and placed into a red bag-lined box. S. H. Biowaste (PA-HC 0096) transports the infectious waste to Bridgeview in Morgantown, PA (PAD175327352). The facility should ensure that the copies of the manifest from the designated facility are maintained on file. The most recent shipment of this waste occurred on 3-12-04.

Glassware is washed using an alkaline soap. The facility is in communication with the POTW. The POTW is ^{accepting} conducting quarterly sampling ^{events}. The wastewater from the washings is a calcium phosphate solution.

The facility will also dispose residual filters used with the calcium phosphate slurry mixtures and off-spec bone cement. The quantities of these waste streams have not yet been determined. However, the facility does not believe the amount of residual waste will exceed thirteen tons per year.

As this time, violations have not been cited. A follow-up inspection will be conducted so as to ensure full compliance after one month has passed.

This inspection report is notice of the findings of an inspection conducted by a representative of the Department. This report is formal notification of any violations observed during the inspection. Additional notification of violations may be issued concerning either violations noted herein, or other violations identified as a result of review of laboratory analyses or Department records.

This report does not constitute an order or other appealable action of the Department. Nothing contained herein shall be deemed to grant or imply immunity from legal action for any violation noted herein.

Signature by the person interviewed does not necessarily imply concurrence with the findings on this report, but does acknowledge that the person was shown the report or that a copy was left with the person.

Person interviewed (signature) Bryan Lee

Date 4/8/04

Inspector (signature) Andrew Sinclair

Date 4-8-04



**ACKNOWLEDGEMENT OF NOTIFICATION
OF REGULATED WASTE ACTIVITY
(VERIFICATION)**

This is to acknowledge that you have filed a Notification of Regulated Waste Activity for the installation located at the address shown in the box below to comply with Section 3010 of the Resource Conservation and Recovery Act (RCRA). Your EPA Identification Number for that installation appears in the box below. The EPA Identification Number must be included on all shipping manifests for transporting hazardous wastes; on all Biennial Reports that generators of hazardous waste, and owners and operators of hazardous waste treatment, storage and disposal facilities must file with EPA; on all applications for a Federal Hazardous Waste Permit; and other hazardous waste management reports and documents required under Subtitle C of RCRA.

EPA I.D. NUMBER

+

PAD174204792

05/19/98

INSTALLATION ADDRESS

BCA BIOPOL INTL
1230 WILSON DR
WEST CHESTER , PA 19380
BUD WEBB PURCH AGENT

1230 WILSON DR
WEST CHESTER , PA 19380



**ACKNOWLEDGEMENT OF NOTIFICATION
OF HAZARDOUS WASTE ACTIVITY
(VERIFICATION)**

This is to acknowledge that you have filed a Notification of Hazardous Waste Activity for the installation located at the address shown in the box below to comply with Section 3010 of the Resource Conservation and Recovery Act (RCRA). Your EPA Identification Number for that installation appears in the box below. The EPA Identification Number must be included on all shipping manifests for transporting hazardous wastes; on all Annual Reports that generators of hazardous waste, and owners and operators of hazardous waste treatment, storage and disposal facilities must file with EPA; on all applications for a Federal Hazardous Waste Permit; and other hazardous waste management reports and documents required under Subtitle C of RCRA.

EPA I.D. NUMBER

+ PAD174204792

INSTALLATION ADDRESS

CHILDERS, DAN MGR QA
ORGANON TEKNIKA CORPORATION
1230 WILSON DR
WEST CHESTER PA 19380

1230 WILSON DR
WEST CHESTER PA 19380